

Remarks

Preliminary Comments.

Reconsideration of the above-identified patent application, as amended, is respectfully requested. Claims 33-38 were indicated in the Office Action as being pending in the case and being rejected on certain grounds. Applicant has cancelled claims 33-38, and the rejections of those claims are therefore obviated. Applicant reserves the right to pursue those or other claims in a subsequent application. Applicant has submitted new claims 39-67, which are believed to be patentable over the cited grounds of rejection for reasons set forth hereafter.

This case is a reissue application filed with respect to US Patent No. 5,997,817. This patent issued with claims 1-32. Applicant understands from the grant of this reissue procedure and the recently issued Office Action that these original claims 1-32 remain patentable and therefore are not currently at issue. Applicant would appreciate the Examiner's confirmation of this understanding as the claims 1-32 were not mentioned in the Office Action.

Patentability of New Claims.

Claims 39-67 are directed to the concept set forth in the application pertaining to the ability to follow the flow of fluid, typically blood, as it enters a test strip. As noted in the pending claims, the test strip is of a type that is filled from an edge and the progress of the fluid can be viewed from the entry port up to a "fill line" that indicates that a sufficient amount of fluid has been received for testing purposes. This provides several distinct advantages for the user. For example, the ability to view the fluid flow is an immediate confirmation that the fluid has been properly dosed to the entry port. The visualization of the fluid flow also provides direct feedback that the test strip is functioning properly to

allow the fluid to wick into the strip, as by capillary action. The time it takes for the fluid to flow, and any irregularities in the movement of the fluid, will also provide indications of whether the test strip appears to be functioning appropriately. Finally, the success of the fluid in reaching the fill line will provide direct confirmation that the amount of fluid received within a test strip is sufficient to conduct a reliable test. It may even be possible for a user to quickly dose additional amounts of fluid to the test strip to make up for an inadequate initial supply of fluid, thereby avoiding having to use another test strip.

The primary reference cited against the cancelled claims was the Galen et al. Patent. The Galen Patent describes a top loading test strip in which sample is applied through a hole 6 in the top support 1. The sample may pass through holes 7 in intermediate layers 2, 3 and/or 4, and through blood separation layers 9 and buffer pad 13 to indicator (dye) pad 14. The test reaction at the dye pad 14 can then be detected at the underside at bottom support 5. The Galen Patent describes that the bottom support may be, e.g., transparent such that the optical detection can occur through the support, or alternatively a hole may be provided if the bottom support is opaque. The Galen Patent therefore does teach that a sample may be optically accessible at a point where the reaction occurs, as is inherent in an optical test strip. However, the Galen Patent does not teach the visualization of the fluid flow to provide feedback as to the progress and sufficiency of the fluid. Further, the Galen Patent does not describe or suggest an edge fill test strip in which the fluid flow is visible as it moves laterally through a capillary fill chamber to a fill-to-here line which indicates that a sufficient amount of fluid has been received for testing purposes.

The §112 ground for rejection of the prior claims is avoided by the present claims. All of the claims include the limitation that the test strip includes a test reagent contained

in a capillary test chamber. The references in the preambles of the claims are therefore satisfied as to the provision of a “test strip” for testing a bodily fluid.

The specification variously describes the nature and function of the test strip with regard to the monitoring of the filling of the capillary chamber in the inventive test strip. In one sense, the test strip provides a “fill line” that provides a direct, visual confirmation that a sufficient amount of fluid has been received by the test strip. For example, claim 39 recites that the

“filling of liquid to the fill line indicates sufficient filling of the capillary test chamber for the test strip to be useful in testing the bodily fluid.”

In correspondence to this language, the specification (with references to the patent text) indicates that the strip includes “a transparent or translucent window that operates as a ‘fill to here’ line, thereby identifying when enough test sample . . . has been added to the test chamber to accurately perform a test.” Column 1, lines 63-67. Similarly, at column 1, line 67 to column 2, line 4, it is indicated that the strip “represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip.” At column 8, lines 61-67, the specification further states that the strip provides “feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample.”

It is therefore apparent that the present claims readily distinguish over the Galen Patent. The claimed invention relates to an edge fill device in which the entering fluid is visualized as it moves toward a fill line, and that fill line provides direct feedback to the user that a sufficient amount of fluid has been dosed to the test strip for it to be useful in testing the fluid.

The case now includes three independent claims 39, 56 and 61 directed to various aspects of this concept. For example, claim 39 refers to a test strip that includes an opaque portion and a transparent or translucent portion which both overlie the capillary test

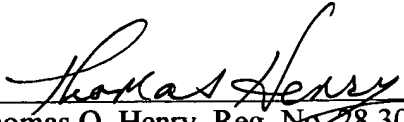
chamber and together define a fill line extending across the capillary test chamber, the progress of liquid to the fill line indicating sufficient fluid for conducting a test. Claim 56 covers a test strip having a transparent or translucent portion overlying the capillary test chamber and an opaque fill line positioned to indicate sufficient filling of the capillary test chamber. Claim 61 applies to a test strip having a transparent or translucent portion and an opaque portion together defining a fill line that indicates a sufficient amount of fluid to accurately perform a test. All of these claims, and therefore the claims dependent thereon, are patentably distinguishable over the cited references based upon these elements, and further in providing a test strip that has an edge fill chamber covered with a transparent or translucent portion through which the movement of the fluid into and through the capillary test chamber can be visualized.

The claims are also distinguishable based on other limitations. Claim 1, for example, requires that the fill line is positioned intermediate the length of the capillary test chamber. Claims 42, 57 and 62 provide that the transparent or translucent portion extends inwardly from the sample application port. Claims 46, 58 and 63 state that the test strip includes a vent hole, and claims 47, 59 and 64 provide that the fill line is positioned between the sample application port and the vent hole. These and other limitations contained throughout the claims provide further patentable distinctions over the cited art, including specifically the Galen Patent.

For at least the foregoing reasons, applicant submits that the present invention is patentable over the prior art, and allowance of the claims pending in the case is respectfully requested. Applicant has appended to this amendment a table showing the status of the claims, and the support in the specification for the added claims.

Reconsideration of the application in view of this response is respectfully requested.

Respectfully submitted,

By: 
Thomas Q. Henry, Reg. No. 28,309
Woodard, Emhardt, Moriarty, McNett & Henry LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137
(317) 634-3456

Claim Status and Support Table

Claim No.	Status	Sample Locations of Support (referencing issued patent)
1	Pending	Originally issued patent claim
2	Pending	Originally issued patent claim
3	Pending	Originally issued patent claim
4	Pending	Originally issued patent claim
5	Pending	Originally issued patent claim
6	Pending	Originally issued patent claim
7	Pending	Originally issued patent claim
8	Pending	Originally issued patent claim
9	Pending	Originally issued patent claim
10	Pending	Originally issued patent claim
11	Pending	Originally issued patent claim
12	Pending	Originally issued patent claim
13	Pending	Originally issued patent claim
14	Pending	Originally issued patent claim
15	Pending	Originally issued patent claim
16	Pending	Originally issued patent claim
17	Pending	Originally issued patent claim
18	Pending	Originally issued patent claim
19	Pending	Originally issued patent claim
20	Pending	Originally issued patent claim
21	Pending	Originally issued patent claim
22	Pending	Originally issued patent claim
23	Pending	Originally issued patent claim
24	Pending	Originally issued patent claim
25	Pending	Originally issued patent claim
26	Pending	Originally issued patent claim
27	Pending	Originally issued patent claim
28	Pending	Originally issued patent claim
29	Pending	Originally issued patent claim
30	Pending	Originally issued patent claim
31	Pending	Originally issued patent claim
32	Pending	Originally issued patent claim
33	Cancelled	Not applicable
34	Cancelled	Not applicable
35	Cancelled	Not applicable
36	Cancelled	Not applicable
37	Cancelled	Not applicable
38	Cancelled	Not applicable
39	Pending	Column 1, lines 63-67; column 4; lines 37-45; column 8, lines 55-59
40		Column 2, lines 10-14
41		Column 5, lines 3-5; column 8, lines 37-47
42		FIGS. 1, 2, 3I
43		Column 2, lines 5-6

44		Column 8, lines 55-59
45		FIGS. 2, 3H, 3I, 5
46		Column 3, lines 1-2
47		FIGS. 2, 3I
48		Column 3, line 55 to column 4, line 10
49		Column 4, lines 36-41
50		Column 4, lines 36-41
51		FIGS. 1, 2
52		Column 3, line 55 to column 4, line 10
53		Column 4, lines 36-41
54		Column 4, lines 1-8
55		Column 5, lines 3-9
56		Column 1, lines 63-67; column 4, lines 37-45; column 8, lines 55-59
57		FIGS. 1, 2, 3I
58		Column 3, lines 1-2
59		FIGS. 2, 3I
60		Column 3, line 55 to column 4, line 10
61		Column 1, line 63 to column 2, line 2; column 4, lines 37-45; column 8, lines 55-67
62		FIGS. 1, 2, 3I
63		Column 3, lines 1-2
64		FIGS. 2, 3I
65		Column 3, line 55 to column 4, line 10
66		Column 1, lines 63-67; column 4; lines 37-45; column 8, lines 55-59
67		Column 1, lines 63-67; column 4; lines 37-45; column 8, lines 55-59